

REMARKS

Claims 1-5, 8-30, and 34-46 are pending in the application. In the final Office Action electronically sent May 13, 2009 the pending claims have been rejected as being obvious under 35 U.S.C. § 1.03(a) to various combinations of U.S. Patent Nos. 6,213,949 to Ganguly et al. (hereinafter Ganguly), 6,905,467 to Bradley et al. (hereinafter Bradley), and 7,041,059 to Chalana et al. (hereinafter Chalana).

In response the Applicants have amended the independent claims and certain dependent claims to which the Applicants believe are non-obvious, novel, fully enabled, and accordingly allowable.

The Applicant requests entry of the claim amendments and urges a finding of allowability thereto.

CLAIM REJECTIONS UNDER 35 U.S.C. § 103(A)

Claims 1-15 and 17-46 are rejected by the combination of Ganguly and Bradley. Claims 1, 20, 24, and 44 are independent claims among the rejected claims.

Dependent claim 16 of the Applicant is rejected by the combination of Bradley and Chalana.

Ganguly, according to the Examiner, teaches a "means for determining body cavity height and depth (Col 6 Line 5-Col 8 Line 25), as well as filling degree based on known values stored from a patients history (Col 8 Line 35-50). However, Ganguly requires curve fitting routines to measure bladder shape, determine area, and then volume by calculating the summed weights of the planar areas (see Ganguly's Figures 4, 5; col 2, lines 48-60 and col 4, lines 37-43).

However, the volumes recorded in the patient history of Ganguly is that of a particular patient whose volumes are acquired after-the-fact of ascertaining (measuring) via the

methodology of Ganguly, but not, as McMorow teaches, the *a priori* utilization of computer accessible look-up tables having calibration factors (of other conglomerate patient histories) to determine fluid volumes from calculated height and depths of the body cavity. McMorow also doesn't require curve fitting algorithms in order to obtain the height and depth values.

The Examiner is asserting that Bradley teaches per col 19, line 25-col 24, line 30 "a summing or exclusion of certain waveforms received from the sample so as to allow for only acquisition of data relating to specific tissues or fluids being investigated". Despite this Examiner assertion, a word search for fluid, fluids, liquid, and liquids and found these terms absent in this specific cited region of Bradley. However, Bradley does teach elsewhere that fluids are a primary source for ultrasound harmonics due to non-linear distortion. Nonetheless, Bradley doesn't teach McMorow's teaching whereby only that portion of echo signals of insonified organ cavities are selected for having been reflected by a organ cavities posterior wall in which these posterior wall reflected ultrasound waves also pass through the fluid occupying the cavity and thence through the anterior wall for collection by the at least one ultrasound transducer. Bradley also fails to teach or suggest determining a fluid volume, much less determining a fluid volume based on determined harmonic-energy values. As such, Bradley fails to supply the teachings missing from Ganguly, namely determining at least one harmonic energy level value associated with echoes from a cavity and calculating a fluid volume contained in the cavity based upon the at least one harmonic energy level value associated with an echo having passed through the fluid. Bradley also doesn't teach what Applicant McMorow teaches of the use of look-up tables where an organ cavity's height and depth are associated with a listing of calibration factors in order to calculate the residing fluid volume therein.

Chalana is being invoked by the Examiner against dependent claim 16 concerning battery powered operations of US transducers and that Chalana's transducers have a bandwidth capable of capturing US harmonic ranges, and that Chalana's transducers and Ganguly's calculation system are obvious. Chalana doesn't teach what Applicant McMorow teaches of *how* to

calculate the fluid volume contained in the body cavity based upon the at least one harmonic energy level value associated with the select harmonic echoes having passed through the fluid as a function of the calibration factors of the look-up table associated with the calculated height and depth of the body cavity.

Referencing the instant application's U.S. Patent Application Publication No. US 2006/0111633 A1 to McMorow in contrast to Ganguly, Bradley, and Chalana, Applicant McMorow teachings are directed to fast measurements of body cavity heights and depths that neither requires time-intensive nor computation-intensive curve fitting and 3-D measuring technologies. McMorow teaches a system that makes a minimal insonification (paragraph 0019's "...a few ultrasound beams...") from either a single mechanical sweeping transducer (Figures 7, 9) or a few fixed transducer assemblies (Figures 1, 2, 3, 6) positioned against the patient's skin, then determining that portion of returning echoes collected by the transducer to have been reflected from the posterior wall and transited through the body cavity lumen, any fluid residing in the body cavity lumen, and finally through the body cavity's anterior wall for the purposes of measuring or quickly determining body cavity Height and Depth (paragraphs 0019, 0035, 0037, and 0041's ultrasound beams associated with "useful transducers") derivable from ultrasound signals traceable to select echoes being reflected from a body cavity's posterior wall and transiting through the body cavity's fluid and anterior wall. Once the H & D of the body cavity is determined, fluid containing volumes residing in the body cavity are rapidly determined from association with a computer assessable calibrated look-up table (paragraphs 0041, 0048).

Claim 1 is amended, in view of Applicant's teachings, to claim an apparatus *configured to measure a fluid volume contained in a body cavity* comprising "at least one transducer assembly positioned in view of *the* body cavity and configured to transmit ultrasound of at least one acoustic power having a fundamental frequency to the body cavity, receive echoes having a harmonic frequency and the fundamental frequency reflected from surfaces associated with the body cavity, and convert the fundamental and harmonic frequency echoes into fundamental and

harmonic signals; and a computer in signal communication with the at least one transducer assembly, the computer having *access to a look-up table of calibration factors and executable signal processing software with programmed instructions to acquire select harmonic echoes reflecting from the posterior wall, the lumen, and the anterior wall of the body cavity*, determine at least one harmonic energy level value associated with the *select echoes*, *to calculate a height and a depth of the body cavity associated with the select harmonic echoes*, and to calculate the fluid volume contained in the body cavity based upon the at least one harmonic energy level value associated with *the select harmonic echoes having passed through the fluid as a function of the calibration factors of the look-up table associated with the calculated height and depth of the body cavity*” (emphasis added). Dependent claims 10-14 have been amended to maintain antecedent basis and/or to claim additional limitations of the look-up table. Dependent claims 2-5, 8-9, and 15-19 remain in previously presented form.

Applicant asserts that independent claim 1 is novel, non-obvious, fully enabled and allowable over the combination of Ganguly and Bradley. Applicants similarly posit that dependent claims 2-5, 8-9, and 15-19 inherit the allowability of claim 1.

Claim 20 is amended, in view of Applicant’s teachings, to claim *a method to determine a fluid volume occupying a body cavity* comprising “positioning at least one transducer assembly in view of *the body cavity*; transmitting, with the at least one transducer assembly, a fundamental ultrasound frequency of at least one acoustic power to the body cavity; receiving, with the at least one transducer assembly, echoes having the fundamental ultrasound frequency and at least one harmonic frequency thereof associated with the body cavity; converting the received ultrasound echoes into fundamental signals and harmonic signals; *selecting the fundamental signals and the harmonic signals derived from the ultrasound echoes that have reflected from the posterior wall of the body cavity, transited through the fluid contained within the body cavity, and transited through the anterior wall of the body cavity to the at least one transducer assembly*; measuring a height and a depth of the body cavity from the selected fundamental and

harmonic signals; and calculating the fluid volume contained in the body cavity as a function of associating the height and the depth with calibration factors in a look-up table (emphasis added)”). Dependent claims 10-14 have been amended to maintain antecedent basis and/or to claim additional limitations of the look-up table. Dependent claims 21-23 remain in previously presented form.

Applicant asserts that independent claim 20 is novel, non-obvious, fully enabled and allowable over the combination of Ganguly and Bradley. Applicants similarly posit that dependent claims 2-5, 8-9, and 15-19 inherit the allowability of claim 20.

Claim 24 is amended, in view of Applicant’s teachings, to claim an apparatus *to determine a fluid volume occupying a bladder* comprising “at least one transducer assembly positioned in view of *the* bladder and configured to transmit ultrasound of at least one acoustic power having a fundamental frequency to the bladder, receive echoes having a harmonic frequency and the fundamental frequency reflected from surfaces associated with the bladder, convert the fundamental and harmonic frequency echoes into fundamental and harmonic signals, *and identifying from the fundamental and harmonic signals those deriving from echoes having reflected from the posterior wall of the bladder and transiting through the fluid volume and anterior wall of the bladder*; and a computer in signal communication with the at least one transducer assembly, the computer having *access to a look-up table of calibration factors and* executable signal processing software with programmed instructions to determine at least one harmonic energy level value associated with the echoes and to *measure a bladder height and a bladder depth and to calculate the fluid volume contained in the bladder based upon the at least one harmonic energy level value associated with an echo having passed through the fluid as a function of associating the bladder height and the bladder depth with the calibration factors in the look-up table*” (emphasis added). Applicant asserts that independent claim 24 is novel, non-obvious, fully enabled and allowable over the combination of Ganguly and Bradley. Applicants similarly posit that dependent claims 26-30 and 34-43 inherit the allowability of claim 24.

Claim 44 is amended, in view of Applicant's teachings, to claim a method *to determine a fluid volume occupying a body cavity* comprising "positioning at least one transducer assembly in view of a body cavity; transmitting a fundamental ultrasound frequency of at least one acoustic power to the body cavity; receiving echoes having the fundamental ultrasound frequency and at least one harmonic frequency thereof associated with the body cavity; converting the received ultrasound echoes into fundamental signals and harmonic signals; *identifying among the fundamental and harmonic signals those being associated with select echoes having reflected from the posterior wall of the body cavity and transited through the fluid contained within the body cavity and the anterior wall of the body cavity*; determining at least one harmonic energy level value associated with the echoes; *measuring a height and a depth of the body cavity from signals derived from the select echoes*; and calculating a fluid volume contained in the cavity based upon the at least one harmonic energy level value associated *the select echoes using calibration factors contained in a look-up table to convert the height and the depth to the fluid volume*" (emphasis added).

Applicant asserts that independent claim 44 is novel, non-obvious, fully enabled and allowable over the combination of Ganguly and Bradley.

Claim 45 is amended, in view of Applicant's teachings, to claim a method for detecting a body cavity of a subject, measuring the volume of the body cavity and a fluid volume contained in the body cavity comprising "positioning at least one transducer assembly in view of the body cavity; transmitting a fundamental ultrasound frequency of at least one acoustic power to the body cavity; receiving echoes having the fundamental ultrasound frequency and at least one harmonic frequency thereof associated with the body cavity; converting the received ultrasound echoes into fundamental signals and harmonic signals; *identifying among the fundamental and harmonic signals those being associated with select echoes having reflected from the posterior wall of the body cavity and transited through the fluid contained within the body cavity and the anterior wall of the body cavity*; *measuring a height and a depth of the body cavity from signals*

derived from the select echoes; determining boundary information of the cavity from the harmonic signals in terms of the depth, the height, and a correction factor, K obtainable from a look-up table; and calculating the fluid volume from a calibration curve obtainable from the look-up table"(emphasis added).

Applicant asserts that independent claim 45 is novel, non-obvious, fully enabled and allowable over the combination of Ganguly and Bradley. Applicants similarly posit that dependent claim 46 inherits the allowability of claim 45.

CONCLUSION

Applicants assert that pending claims 1-5, 8-30, and 34-46 are novel, non-obvious, fully enabled and accordingly in condition for allowance. A Notice of Allowance is therefore earnestly solicited.

If the Examiner has any questions, the Examiner is invited to contact the Applicant's agent listed below.

Respectfully submitted,

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